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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,229	04/08/2004	Tara Ziolo	5490E-000365	9402
27572 7590 07/23/2010 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 PLOOMETED BILLS ML48202			EXAMINER	
			COTRONEO, STEVEN J	
BLOOMFIELD HILLS, MI 48303			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			07/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/821,229	ZIOLO ET AL.				
Office Action Summary	Examiner	Art Unit				
	STEVEN J. COTRONEO	3733				
The MAILING DATE of this communication app	pears on the cover sheet with the c	orrespondence address				
Period for Reply	VIO OET TO EVENE AMONTHI	0) OD THIDTY (00) BAYO				
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period value of the reply within the set or extended period for reply will, by statute any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>12 Ju</u>	<u>aly 2010</u> .					
• • • • • • • • • • • • • • • • • • • •	· · · · · · · · · · · · · · · · · · ·					
3) Since this application is in condition for allowar	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>47-66</u> is/are pending in the application	n.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>47-66</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	e <b>r</b> .					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	caminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)☐ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the prior	·	ed in this National Stage				
application from the International Bureau						
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
Attachment(s)	_					
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5)					
Paper No(s)/Mail Date	6) 🔲 Other:					

### **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/12/2010 has been entered.

# Response to Amendment

The Declaration filed on 5/28/2010 under 37 CFR 1.131 is sufficient to overcome the Duong et al. reference.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 47-66 rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US 2001/0014807) in view of Nielson (US 3,515,418).

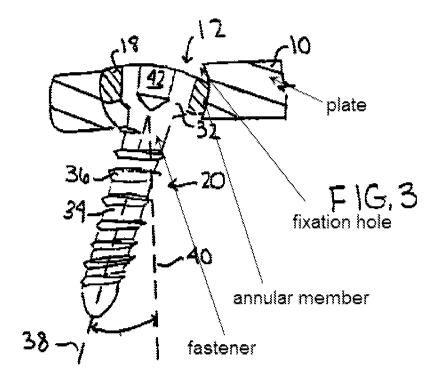
Wagner et al. discloses a bone fixation apparatus (see fig 3 below) comprising: a bone fixation plate (fig 3, 10) having a fixation hole (fig 3, 12); a fastener shaft (fig 3, 20) passing through the fixation hole, the fastener shaft having a longitudinal axis, the fastener shaft including a head portion (fig 3, 32) and a bone-engaging portion; and an

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annular member (fig 3, 18) received in the fixation hole, the annular member circumferentially surrounding the first portion of the fastener shaft, wherein in an unexpanded position the fastener shaft and the annular member can rotate freely about the axis of the fastener shaft and collectively seat in the fixation hole at various angles relative to the fixation plate, and wherein in an expanded position the fastener shaft and annular member are prevented from backing out of the fixation hole (paragraph 59). The apparatus has a semi-constrained mode wherein the annular member is free to move in the plate and a constrained mode where the annular member is fixed (paragraph 59, "ring to expand such that the orientation of the bone screw relative to the plate is fixed."). The annular member has an outer surface and the fixation plate has an inner surface that is spherical (fig 3 and paragraph 46, "ball and socket joint"). The fixation plate is used for the vertebrae (title). The annular member has an expanded position that allows the annular member to rotate within the fixation hole (paragraph 49) and an expanded position that fixes the fastener to the hole (paragraph 59).

Wagner et al. discloses the claimed invention with the annular member being expanded by a threaded engagement between the annular member and the fastener head. Wagner et al does not disclose the mechanism of expansion wherein the fastener shaft includes a first portion having an outer surface defining a first cam, and the annular member having an inner surface defining a second cam for cooperating with the first cam to selectively expand the annular member in a radial direction from an unexpanded position to an expanded position.

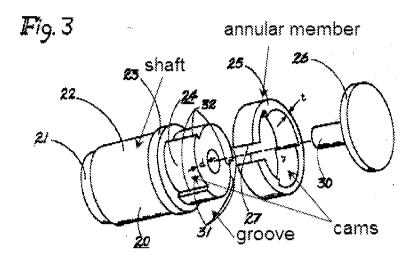
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Nielson discloses the mechanism (see fig 3 below) wherein a shaft (fig 3, 20 and 30) includes a first portion (fig 3, 24) having an outer surface defining a first cam (fig 3, 31), and the annular member (fig 3, 25) having an inner surface defining a second cam (see fig 3 below) for cooperating with the first cam to selectively expand the annular member in a radial direction from an unexpanded position to an expanded position (col. 4, II. 10-19). The cams have three continuous lobes (fig 3 and col. 3, II. 39-40, "three cam surfaces, each constituting continuous curve surfaces"). The annular member selectively moves to permit motion from the unexpanded to the expanded position by rotation. The shaft defines a groove that the annular member is carried in (fig 3, between 25 and 26). When assembled the groove is spaced apart from the ends (fig 3, 21 and 26).

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It would have been obvious at the time of the invention to one of ordinary skill in the art to substitute threaded expansion engagement of Wagner et al. with the cam mechanism in view of Nielson because threaded expansion and the expansion caused by a cam are mere functional equivalents, and because such a substitution of one for the other would have achieved the same predicable result of expanding the annular member to fix the shaft within the a hole.

# Response to Arguments

Applicant's arguments filed 7/12/2010 have been fully considered but they are not persuasive. The applicant argues that Wagner discloses movement of the bone screw causes expansion of the ring and that the movement of the ring is not independent from movement of the bone screw. The examiner respectfully disagrees. Firstly movement is relative and the ring can move and the screw can be held in place to cause the ring to expand. Secondly the applicant does not consider the Nielson reference where the ring is the part that rotates. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking

references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to claim 65, the applicant argues that the shaft does not have a circumferential groove that is separate from the ends of the shaft. The examiner has shown above in bold where the groove is. The examiner is considering the shaft of Nielson to be a two part shaft including parts 20 and 30.

The applicant also argues that Wagner and Nielson are non-analogous art. The examiner respectfully disagrees. In response to applicant's argument that Nielson is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Nielson is pertinent because both Wagner and Nielson are both locking mechanism aimed at locking a shaft in a hole. The applicant further argues that Nielson is a temporary locking mechanism and Wagner is a permanent locking mechanism. The examiner respectfully disagrees. Both locking mechanisms will remain locked until the user actively unlocks the mechanism.

The rejection is deemed proper.

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#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./ Examiner, Art Unit 3733

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734